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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,254	03/27/2001	Scott A. Waldman	TJU-2414	2093

7590

03/12/2002

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EXAMINER

DAVIS, NATALIE A

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/819,254

Applicant(s)

WALDMAN ET AL.

Examiner

Natalie A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-24 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicant's election of Group III, claims 25-32 Species B (PCR) in Paper No. 10 is acknowledged. Applicant request reconsideration of the election of species, as Species B (PCR) is a subspecies of A (detection of gene transcription product). This is found to be persuasive, Species B and C will be rejoined.

The requirement is still deemed proper and is therefore made FINAL. Claims 25-27 and 29-31, Species A and B and are being examined as belonging to the elected Group III, while claims 1-24, 28, 32-33 are withdrawn from examination as being drawn to a non-elected invention.

Information Disclosure Statement

The information disclosure statements have been considered. A signed copy is attached hereto.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-27 and 29-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. In claims 25 and 29, the "steps of examining a sample of stomach/esophagus tissue to detect the presence of SI" are unclear. The claim does not set forth steps, which are needed for detection.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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2. Claims 25, 28, 29, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Silberg, et al., (1997).
3. Silberg, et al teach the detection of CDX1 via immunohistochemistry in adenocarcinomas of the stomach and esophagus, using antibodies specific for a peptide epitope on CDX1 (abstract). Accordingly, the prior art reference anticipates the invention as claimed.

maintain

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 25-27 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silberg, et al. (1997) in view of Wu, et al. (1998).

? 1993 see 892

6. Silberg, et al teach the detection of CDX1 via immunohistochemistry in adenocarcinomas of the stomach and esophagus (abstract). Silberg, et al. does not teach CDX1 detection using PCR. However, Wu, et al. teach detection of SI mRNA by PCR (Table 1) in 76% of Barrett's mucosa specimens, 82% of esophageal adenocarcinomas (p. 839, col. 1 last paragraph). It would have been obvious at the time of the invention to use PCR instead of immunohistochemistry to detect CDX1 in a method to diagnosis stomach and esophageal cancer. One would have been motivated to use PCR since Wu, et al. teach PCR as a highly sensitive and specific assay for the determination of the presence of SI transcript (p. 838, col. 2, paragraph 1) and because both Silberg, et al., and Wu, et al. teach detection methods for the diagnosis of stomach and esophageal cancer. One would be further motivated to combine the teachings and use PCR to detect CDX1 since Silberg, et al. teach an association between CDX1 and SI, as gene transcription is regulated by CDX1 binding to the SI promoter (p. 484, col. 1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, PhD

March 8, 2002



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